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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,112

08/02/2005

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Q88453

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23373 7590 09/30/2008
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EXAMINER

CHRISS, JENNIFER A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,112	Applicant(s) MIYOSHI ET AL.	
	Examiner JENNIFER A. CHRISS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 4, 6 - 8, 10 - 13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/13/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's Amendments and Accompanying Remarks filed on August 13, 2008 has been entered and carefully considered. Claims 5 and 9 are cancelled, claims 11 – 13 are withdrawn and claims 1 – 4, 6 – 8 and 10 are pending. In view of Applicant's amendments to the claims and an updated search, the Examiner has withdrawn the previously set forth rejection and has applied newly discovered art which the Examiner believes better reflects Applicant's invention. The invention as currently claimed is not found to be patentable for reasons herein below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement filed August 13, 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in

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the English language. It has been placed in the application file, but the information referred to therein has not been considered. Please submit a translation of the document or provide a concise statement of relevance in English for the following documents: JP 3-167306, JP 36-17403, JP 9-217232, and JP 60-167969. Furthermore, the Foreign Communications from the Japanese Patent Office and the Taiwanese Office Action are not considered because they are not listed on the IDS and they are not accompanied with a translation or a statement of relevance in English.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1 and 6 require “wherein the number-average molecular weight of the organic compound having a plurality of hydroxyl groups is not less than 62 or more than 300”. What are the units for the number-average molecular weight? Is it g/mole or kg/mole (Daltons or kDaltons)? For purposes of examination at this time, the Examiner will assume that the units are g/mol, however, if this is what the Applicant intends, the claim must amend the claims accordingly. Please note that any amendments made must have support in the originally filed Specification.

Claim Rejections - 35 USC § 103

7. Claims 1 – 3 and 6 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (US 4,919,809).

Yamamoto et al. is directed to a hollow fiber membrane useful for hemofiltration therapy (Abstract).

As to claims 1 and 6, Yamamoto et al. teach a hollow fiber having a wet porosity of 60 – 95% (column 4, lines 64 – 69) comprising cuprammonium cellulose and a solution of polyethylene glycol having an average molecular weight between 150 to 600 (column 7, lines 13 – 61 and column 8, lines 1 – 10). Yamamoto et al. teach that the hollow fibers can be used to create a separating membrane for a hemopurification module (column 9, lines 10 – 40). Yamamoto et al. also teach a particular Example using cuprammonium cellulose, trichlorotrifluoroethane as the hollow portion forming agent and polyethylene glycol 200 (Examples 6 and 10). The Examiner equates the cuprammonium cellulose to Applicant's "hydrophobic solvent-soluble polymer" and the polyethylene glycol having an average molecular weight between 150 to 600, with an example of 200 to Applicant's "organic compound having a plurality of hydroxyl groups...wherein the number average molecular weight of the organic compound having a plurality of hydroxyl groups is not less than 62 or more than 300". As shown in Table 1, the fiber has a thickness of 20 microns (columns 15 – 16).

As to claims 2 – 3 and 7 - 8, Yamamoto et al. teach that the hollow portion forming agent or Applicant's "hydrophobic solvent" can be trichlorotrifluoroethane

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(column 11 and column 12, Example 6).

Yamamoto et al. fails to teach that the average fiber diameter is between 0.1 and 20 microns. It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize diameter since it has been held that, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The burden is upon the Applicant to demonstrate that the claimed diameter range is critical and has unexpected results. In the present invention, one would have been motivated to optimize the fiber diameter to 0.1 to 20 microns motivated by the desire to create a porous fiber suitable for a wide range of medical applications using updated technology to create fibers on a smaller scale.

Claim Rejections - 35 USC § 103

8. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (US 4,919,809) in view of ***Contemporary Biomaterials*** edited by Boretos et al.

Yamamoto et al. teach the claimed invention above but fail to teach that the hydrophobic solvent-soluble polymer is selected from the group consisting of polylactic acid, polycaprolactone, polycarbonates, polystyrene and polyarylates.

Contemporary Biomaterials discusses the use of regenerated cellulose hollow fibers such as rayon hollow fibers for hemodialysis (page 243). Contemporary

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Biomaterials indicates that it was discovered that the rayon fibers had toxic long-term effects on the body and new synthetic materials such as polycarbonate was introduced as a replacement and proved to have better blood compatibility (page 244).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute polycarbonate for rayon as discussed in Yamamoto et al. because substitution of one known polymer for another would have yielded predictable result of providing a biocompatible porous fiber having improved blood compatibility.

Response to Arguments

9. Applicant's arguments with respect to claims 1 – 4, 6 – 8 and 10 have been considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Examiner, Art Unit 1794

/J. A. C./
Examiner, Art Unit 1794